

FEB 2 1999

Section 3

2984437

quantex ASO-CRP-RF control II - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
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Contact Person:

Carol Marble
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

December 11, 1998

Name of the device:

quantex ASO-CRP-RF control II

Classification name(s):

862.1660 Quality Control Material (Assayed and Unassayed) Class I

Identification of predicate devices:

K971777 quantex ASO-CRP-RF control

Description of the device/intended use(s):

The quantex ASO-CRP-RF control II is an *in vitro* diagnostic product intended for use with automated instrumentation in monitoring the quality control of results obtained with the quantex ASO plus, quantex CRP plus and quantex RF plus reagents. When the combined control, which contains a known assayed value of antistreptolysin-O, C-reactive protein and rheumatoid factor, is mixed with the quantex ASO plus, quantex CRP plus, or quantex RF plus latex reagent, a clear agglutination occurs which can be measured by turbidimetry.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

The new quantex ASO-CRP-RF control II is substantially equivalent in performance, intended use and safety and effectiveness to the predicate control: quantex ASO-CRP-RF control.

Summary of Performance Data:

In a comparative performance study on a COBAS Mira, the new quantex ASO-CRP-RF control II exhibited excellent within run precision in comparison to the predicate control: quantex ASO-CRP-RF control. Within run %CV for the new control was 2.7% (ASO), 1.6% (CRP) and 1.1 (RF) as compared to within run %CV for the predicate control of 4.8% (ASO plus), 3.5% (CRP) and 1.7% (RF).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 12 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carol Marble
Regulatory Affairs Manager
INSTRUMENTATION LABORATORY COMPANY
113 Hartwell Avenue
Lexington, MA 02421

Re: K984437
Trade Name: quantex ASO-CRP-RF control II
Regulatory Class: I
Product Code: JJT
Dated: December 11, 1998
Received: December 14, 1998

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

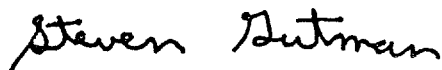
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

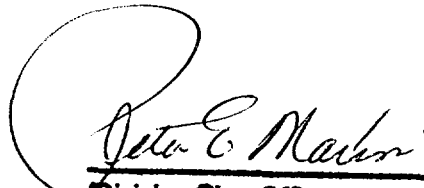
Indications for Use Statement

510(k) Number (if known): K 984437

Device Name: quantex ASO-CRP-RF control II

Indications for Use:

The quantex ASO-CRP-RF control II is an *in vitro* diagnostic product intended for use in the quality control of automated instrumentation to monitor the results obtained with the quantex ASO plus, quantex CRP plus and quantex RF plus reagents using the turbidimetric method.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984437

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.019)

OR Over-The-Counter Use ☐